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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/809,920	03/16/2001	Taka-Aki Sato	0575/51902-A-PCT-US/JPW/A	8743

7590 08/12/2003

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EXAMINER

SCHULTZ, JAMES

ART UNIT	PAPER NUMBER
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1635

11/

DATE MAILED: 08/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/809,920

Applicant(s)

SATO, TAKA AKI

Examiner

J. Douglas Schultz

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 April 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 7, 12, 13, 16, 21, 22 and 98-106 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7, 12, 13, 16, 21, 22 and 98-106 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other:

DETAILED ACTION***Status of Application/Amendment/Claims***

Applicant's response filed April 28, 2003 has been considered. Rejections and/or objections not reiterated from the previous office action mailed November 22, 2002 are hereby withdrawn. The following rejections and/or objections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application.

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Response to Arguments

2. Claims 1-7, 12-16, 21-22 and 98-106 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, and is repeated for the same reasons of record as set forth in the Office action mailed November 22, 2002.

The claims as amended do not significantly alter the breadth of the claimed genus of nucleic acid molecules including nucleic acids encoding any mammalian tumor necrosis factor

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receptor-associated factor (TRAF) protein-interacting hereditary multiple extoses (TREX) protein.

Applicants have traversed the rejection above on the grounds that the specification discloses additional sequences and additional modifications associated with TREX. Applicants direct the examiner's attention to the specification, inter alia, at page 15, line 3 to page 16, line 10, describing different embodiments of the subject invention. These include, but are not limited to, mouse TREX cDNA and protein, also described in Figures 7A-7B, Figures 9A-9B, and disclosed as SEQ ID NO: 1 (Mouse TREX cDNA sequence) and SEQ ID NO:2 (Mouse TREX protein sequence). Applicant further directs the examiner's attention to the specification, inter alia, at page 53, lines 7-33, detailing some of the possible genetic alterations of TREX. These are summarized in Table 3 and include a 9-bp insertion between nucleotide 758 and nucleotide 759, a base substitution of nucleotide 1106 from G to A, a base substitution of nucleotide 1820 from A to G, and a base substitution of nucleotide 2408 from C to T.

In response, the claims are considered to be adequately described for human and mouse sequences, SEQ ID NOS. 3 and 1, but these sequences do not provide a representative number of sequences for the genus of any mammalian TREX as currently claimed.

Applicant states on page 9 that "[t]he claimed genus comprises mammalian nucleic acid molecules encoding a Tumor necrosis factor Receptor-Associated Factor (TRAF) protein-interacting hereditary multiple extoses (EXT) protein (TREX). The disclosed species include full-length cDNAs which are characterized by a TRAF-binding domain, and high homology to the EXT gene family. Applicant maintains that one skilled in the art would easily recognize these necessary common attributes of the claimed genus in view of the disclosed species."

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In response, it is maintained that this information does not provide a complete disclosure to one skilled in the art that would allow for visualization of any nucleic acid sequence encoding the claimed genus of mammalian TREX nucleotide sequences, variants, homologues or isoforms, from species known, unknown, or yet to be described. This is particularly true in light of the fact that even the two sequences provided differ from one another. One of skill in the art would be unable to envision nucleic acid sequences that have TREX activity from the disclosure of TREX-encoding nucleotide sequences from two different sources. As a result, one would necessarily have to resort to *de novo* experimentation to discover the sequence of new nucleic acids encoding proteins having an activity like the disclosed TREX proteins. Neither the specification as filed nor the prior art provide adequate guidance to make or use a nucleotide sequence that retains the function of a TREX protein. Thus, at the time the invention was made, one of skill in the art would not have recognized that applicant was in possession of a representative number of species of any such mammalian TREX encoding nucleic acid of the genus claimed.

1. Claims 1-7, 12-15, 21-22, 101-106 are free of the prior art and are no longer rejected under 35 U.S.C. 102(a) as being anticipated by GenEmbl AF001690, Van Hul et al., Genomics 47 (2), 230-237 (1998) in view of the declaration filed by Dr. Sato filed April 28, 2003. Claims 16 and 98-100 are free of the prior art because the closest prior art, GenEmbl AF001690, Van Hul et al., Genomics 47 (2), 230-237 (1998), does not teach nor fairly suggest the TREX having a genetic alteration as set forth in instant Table 3 (claim 16) nor deletion mutants (claims 98-100). A sequence search of instant SEQ ID NO:3 also revealed that the mRNA/cDNA sequence in GenEmbl AB007042, Saito et al., Biochem. Biophys. Res. Commun. 243 (1), 61-66, 1998,

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was not available until Feb. 13, 1999 and the mRNA/cDNA sequence was not published in the journal article.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. Douglas Schultz whose telephone number is 703-308-9355.

The examiner can normally be reached on 8:00-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on 703-308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

James Douglas Schultz, PhD
August 11, 2003



JOHN L. LeGUYADER
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600